REMARKS

The Examiner provides a single rejection that Claims 1-3 are rejected under 35 USC § 103(a) as allegedly being unpatentable over Quessy et al., United States Patent Application Publication No. 2002/0147196 in view of Guay, D. Am J Geriatric Pharmacotherapy 1:18-37 (September 2003).

I. Guay Is Not Prior Art

The Examiner concludes that "The claims are therefore properly rejected under 35 U.S.C. 103." *Office Action, pg. 4.* The Applicants disagree. References applied to support a 35 USC § 103(a) rejection are subject to the same statutory limitations as for those applied under 35 USC § 102. This rule is summarized in the MPEP as follows:

> Subject matter that is prior art under 35 U.S.C. 102 can be used to support a rejection under section 103. *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) ("it appears to us that the commentator [of 35 U.S.C.A.] and the [congressional] committee viewed section 103 as including all of the various bars to a patent as set forth in section 102.").

MPEP 2141.01. Consequently, a reference may not be considered properly cited under 35 USC § 103(a) unless it satisfies one of the conditions within 35 USC § 102(a) – (g). In general, a properly cited reference must be published and available to the public: i) at least one year before the priority date of the pending application; or ii) within a year of the priority date of the pending application unless comprising the inventor's own work (37 CFR § 1.131) or where inventor conceived and reduced to practice the invention before publication date (37 CFR § 1.132).

In the present Office Action, the Examiner has cited Guay improperly because the Applicants' filing date is before Guay became publically available. The Applicants attach as evidence an abstract from Elsevier's "Science Direct" on-line publication service clearly showing an on-line availability date of November 6, 2003. This date is after the Applicant's filing date (October 30, 2003).

The Applicants, therefore, respectfully request that the Examiner withdraw Guay as a cited reference.

II. Claims 1-3 Are Not Obvious

Furthermore, the fact that Guay is not prior art also moots the pending 35 USC 103(a) rejection because the Examiner admits that Quessy et al. does not teach a composition comprising a combination of oxcarbazepine and bupropion:

> Quessy et al. do not expressly illustrate an example of the composition comprising bupropion and oxcarbazepine ...

Office Action pg. 3. Further, Guay does not teach drug combinations of any type. Consequently, a drug combination comprising oxcarbazepine and bupropion is not taught by Quessy et al. and Guay.[1]

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

Dated: 10/27/2005

Thomas C. Howerton
Registration No. 48,650

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
617.984.0616

[1] The Applicants believe that the Quessy et al./Guay combination does not contain a proper motivation to modify the art for creating the claimed embodiment, and reserve the right to enter such an argument.

The American Journal of Geriatric Pharmacotherapy
Volume 1, Issue 1 , September 2003, Pages 18-37

doi:10.1016/S1543-5946(03)80013-2 Cite or Link Using DOI

Oxcarbazepine, topiramate, zonisamide, and levetiracetam: Potential use in neuropathic pain

David R. P. Guay PharmD

Department of Experimental and Clinical Pharmacology, and Institute for the Study of Geriatric Pharmacotherapy, College of Pharmacy, University of Minnesota, and PartneringCare Senior Services, Division of Geriatrics, HealthPartners, Minneapolis, Minnesota, USA

Accepted 1 July 2003. Available online 6 November 2003.

Abstract

Background: Oxcarbazepine, topiramate, zonisamide, and levetiracetam are the antiepileptic drugs (AEDs) most recently approved by the US Food and Drug Administration. Based on the experience with carbamazepine, gabapentin, and lamotrigine, these newer AEDs are being investigated for the management of neuropathic pain.

Objective: This article reviews preclinical and clinical data on the efficacy and tolerability of these 4 AEDs in the management of neuropathic pain, as well as the pharmacokinetics, drug-interaction potential, adverse effects, and dosing of these agents, with an emphasis on their use in older individuals.

Methods: Relevant studies were identified through a MEDLINE search of the Englidh-language literature published between 1986 and May 2003, a review of the reference lists of identified articles, and abstracts from the annual meetings of the American Academy of Neurology (1986–2002) and the 2003 Annual Meeting of the American Pain Society. Search terms were *oxcarbazepine, topiramate, zonisamide*, and *levetiracetam*.

Results: Oxcarbazepine and topiramate have been effective in animal models of neuropathic pain. Thirty-four publications on the efficacy and tolerability of the 4 agents were identified (25 case reports/case series, 6 randomized parallel-group studies, and 3 randomized crossover studies). The 9 randomized studies were restricted to oxcarbazepine and topiramate, and 23 (68%) publications were available in abstract form only. These preliminary data suggest that the 4 newer AEDs may be useful in a wide variety of neuropathic pain syndromes; however,

additional data, including full-length peer-reviewed reports, are necessary before their true analgesic potential in neuropathic pain can be determined. All 4 agents have pharmacodynamic interactions with other psychotherapeutic drugs, potentiating adverse central nervous system events such as sedation. With the exception of levetiracetam, these drugs also have pharmacokinetic interactions with other drugs, although to a somewhat lesser extent than carbamazepine. These agents have some unique adverse effects not frequently monitored by clinicians, such as hyponatremia, nephrolithiasis, acute myopia with secondary angle-closure glaucoma, and weight loss.

Conclusions: Based on preliminary data, oxcarbazepine, topiramate, zonisamide, and levetiracetam may be useful in the treatment of a wide variety of neuropathic pain syndromes, although full publication of the results of controlled trials is awaited. These agents are associated with specific adverse effects not commonly monitored by clinicians. Of the 4, levetiracetam appears to be easiest to use (ie, no need for dose adjustment in organ dysfunction, no need for laboratory monitoring) and best tolerated, and has not been associated with the unique toxicities seen with oxcarbazepine, topiramate, and zonisamide. The ultimate role of these agents in the therapeutic armamentarium against pain requires further research and experience. In the interim, these 4 agents should be used to treat neuropathic pain in the elderly only when carbamazepine, gabapentin, or lamotrigine cannot be used or when the response to the aforementioned agents is suboptimal.

Author Keywords: oxcarbazepoine; topiramate; zonisamide; levetiracetam; neuropathic pain; antiepileptic drugs

The American Journal of Geriatric Pharmacotherapy
Volume 1, Issue 1 , September 2003, Pages 18-37

This Document
- **Abstract**
- Abstract + References
- PDF (1971 K)

Actions
- E-mail Article

Home | Journals | Books | Abstract Databases | My Profile | Alerts | Help

Contact Us | Terms & Conditions | Privacy Policy